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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/13/2003

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/883,112

Applicant(s)

BECKER ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondenc address --

Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 and 24-31 is/are rejected.
- 7) ☐ Claim(s) 23, 32-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The response filed on May 20, 2003 has been acknowledged and entered.

Withdrawn Rejection(s)

Rejection under 102 (b) for claims 24, 25, 27, 28, 30, 31 is withdrawn herein.

Rejection under 103 (a) for claims 26, 29 is withdrawn herein.

Newgrounds of Rejection(s)

Claim Rejections - 35 USC § 103

Claims 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart et al. (US 5,922,537) in view of Benecke et al. (US 6,149,789).

Ewart has been described above.

However, Ewart fails to teach manipulation of a complex using dielectrophoresis. Ewart also fails to teach sample comprises of water, food, food processing or ore; the manipulation comprises of purification of the sample.

Benecke et al. teaches a process for manipulating microscopic dielectric particles in which particles are exposed to an electric field. (see col. 1, lines 61-67).

It would have been obvious to one of ordinary skills in the art to use the method of Benecke to manipulate dielectric particles such as those of Ewart in an assay for detecting analyte as taught by Ewart. Since Ewart suggests using dielectric particles in assay and it is known in the art that dielectrophoresis is used for manipulating dielectric particles, one of ordinary skills in the art would find it obvious to manipulate the dielectric particles via dielectrophoresis.

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Regarding the limitation of claim 29, if Ewart teaches a separation step, then one of ordinary skills in the art would find it obvious to use the dielectric particles with paramagnetic property to purify sample since separation encompasses a broad range of things to be separated.

Regarding the limitation of claims 21 and 26, the sample comprising of food, water, food processing, food distribution, mineral, and ore, since Ewart teaches, in col. 1, lines 32-35, that detection of analyte in sample may be indicative of a particular condition in microorganisms and higher life forms including animals and humans, one of ordinary skills in the art would find it obvious to detect analytes from a variety of sample sources such as food, water because food and water contain microorganisms and food such meat products are sources from animals.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ewart et al. (US 5,922,537).

Ewart teaches an assay method, sandwich, indirect, competitive or direct assay, using reporter particles such as dielectric particles (see col. 4, lines 6-14). The core particles can be made from a wide variety of inorganic materials including metals such

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as gold, silver, platinum (see col. 5, lines 17-26). The particle core can be encapsulated in a polymer such as polystyrene (see col. 7, lines 20-30). The dielectric particles can be engineered to have one or more dielectric properties or paramagnetic properties and phosphorescent properties (see col. 11, lines 7-13). In the assay, the target analyte is contacted with the reporter particles linked to a recognition molecule that specifically binds the target analyte. Detection is performed by comparison of the dielectric constant of unbound dielectric particles/labels and that of the complexed dielectric particles/labels using a biosensor to measure those properties. (see col. 4, lines 53-65). The dielectric particles/labels contributes the dominant dielectric constant (second dielectric property) in the complex analyte-recognition molecule-dielectric label (see col. 14, lines 33-38). The dielectric property of an unbound dielectric label is the first dielectric property. The recognition molecule/linking element comprises of antibody, hormone, antigen, etc. (see col. 7, lines 54-65). The sample is bodily fluid such as blood (see col. 4, lines 49-51). Ewart also teaches that the dielectric particles/labels move in an electrophoretic field when being applied in a separation method (see col. 11, lines 27-31). Trapping is performed when the particles captures the analyte. Sorting is the same as separating.

Response to Arguments

The arguments filed on May 20, 2003 have been fully considered but not found persuasive.

Regarding the 35 USC 102 rejection anticipated by Ewart, Applicants submit that Ewart fails to disclose or suggest detecting a complex by distinguishing between a

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dielectric property of a microparticle and a dielectric property of a complex. Applicants further state that the Ewart reference reveals that it detects a complex by distinguishing a difference in global device capacitance arising from a complex being added to, or taken away from, a test surface of a biosensor.

The changes in capacitance in Ewart are equivalent to the differences in dielectric properties thus satisfies the requirement of the present invention. Ewart teaches that the change [in capacitance] is determined exclusively by the change in dielectric constant of the particles to the dielectric constant of water in the **complexing layer** (emphasis added). The complexing layer of the present invention fails to exclude water as part of the complex. In fact, the sample of the present invention includes blood, saliva, which consists of some water. Since Ewart discloses the same methods with similar reagents as those of the present invention, the results of the two methods would be the same.

Remarks

Claims 23, 32-35 are free of prior arts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
August 3, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
8/3/03